DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 7, 2015

Pegasus Medical Supply, Inc.
% Michael Lee
President
AcmeBiotechs Co., Ltd.
No. 45, Minsheng Rd. Danshui Town
New Taipei City, 251 TW

Re: K143202
Trade/Device Name: ANGIO-PRESS DVT Compression Device Model Name: IPCS
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: June 4, 2015
Received: June 8, 2015

Dear Michael Lee,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply

with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K143202

Device Name: ANGIO-PRESS DVT Compression Device
Model Name: IPCS

Indications for Use:

The Pegasus Medical Supply Inc. ANGIO-PRESS IPCS Deep Vein Thrombosis (DVT) Compression Devices are intended to increase venous blood flow in patients in order to help prevent deep vein thrombosis.

Prescription Use ___X___ AND/OR Over-The-Counter Use____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

5.1 **Type of Submission:** Traditional

5.2 **Preparation Date:** 29th October 2014

5.3 **Submitter:**

Address: Pegasus Medical Supply, Inc.
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Contact: PAO-MING SHIH
(borisshih@pegasus-pms.com)

Registration number: -

5.4 **Identification of the Device:**

Proprietary/ Trade name:	ANGIO-PRESS DVT Compression Device Model Name: IPCS
Classification Name:	Sleeve, Limb, Compressible
Device Classification:	II
Regulation Number:	870.5800
Panel:	Cardiovascular
Product Code:	JOW

5.5 **Identification of the Predicate Device:**

Predicate Device Name:	VasoPress DVT Supreme Mini, Pump Model No. VP500DM
Manufacturer:	Compression Therapy Concepts, Inc.
Regulation number:	870.5800
Product Code:	JOW
510(k) Number:	K101915

5.6 Intended Use and Indications for Use of the subject device.

The Pegasus Medical Supply Inc. ANGIO-PRESS IPCS Deep Vein Thrombosis (DVT) Compression Devices are intended to increase venous blood flow in patients in order to help prevent deep vein thrombosis.

5.7 Device Description

ANGIO-PRESS DVT Compression Device that counteracts blood stasis and coagulation changes – two of the three major factors that promote deep vein thrombosis (DVT). ANGIO-PRESS DVT Compression Device is a non-invasive mechanical prophylactic system that massages the legs in a wavelike, milking motion that promotes blood flow and deters thrombosis, helping to empty pooled or static blood from the valve cusps of the femoral vein. Fibrinolytic activity is increased, stimulating the release of a plasminogen activator. This therapy typically complements other prophylactic measures, such as ant embolic stockings and anticoagulants.

ANGIO-PRESS DVT Compression Device is used to prevent pooling of blood in a limb by inflating periodically a sleeve around the limb. Therefore, ANGIO-PRESS DVT Compression Device is identified as a compressible limb sleeve.

5.8 Non-clinical Testing

A series of safety tests were performed to assess the safety and effectiveness of the ANGIO-PRESS DVT Compression Device.

Testing Item	Standard and regulations applied
Biocompatibility	ISO 10993-1:2009/Cor. 1:2010(E) Biological evaluation of medical devices – Part 1: Evaluation and testing with a risk management process.
	ISO 10993-5:2009 (E) Biological evaluation of medical devices – Part 5: Tests for *in vitro* cytotoxicity.
	ISO 10993-10:2010 (E) Biological evaluation of medical devices –

	Part 10: Tests for Tests for irritation and skin sensitization.
	ISO 10993-12: 2012 (E) Biological evaluation of medical devices – Part 12: Sample Preparation And Reference Materials.
	ISO/IEC 17025:2005 General Requirements for the Competence of Testing and Calibration Laboratories.
	USP Biological reactivity tests, *in vitro*
Software	IEC 62304 First Edition 2006-05, Medical Device Software - Software Life Cycle Processes. (Software/Informatics)
Electromagnetic Compatibility & Electrical Safety	EN 60601-1-2 : 2007/AC:2010 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.
	IEC 60601-1-2 : 2007 Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests. (General I (QS/RM))
	IEC 60601-1 Medical Electrical Equipment – Part 1:General requirements for basic safety and essential performance
Performance	IEC 60068-2-6 Environmental testing - Part 2-6: Tests - Test Fc: Vibration (sinusoidal)
	IEC 60068-2-27 Environmental testing - Part 2-27: Tests - Test Ea and guidance: Shock
	ISTA 2A Standard
	IEC 60068-2-14: 2009 Environmental testing - Part 2-14: Tests - Test N: Change of temperature.
Risk Management	ISO 14971 Medical Devices - Application Of Risk Management To Medical Devices.
	IEC 60812 Analysis Techniques For System Reliability – Procedure For Failure Mode And Effects Analysis (Fmea).
Usability	IEC 60601-1-6 Edition 3.1 2013-10, Medical Electrical Equipment - Part 1-6: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Usability.

	IEC 62366 Edition 1.1 2014-01, Medical Devices - Application Of Usability Engineering To Medical Devices.

All the test results demonstrate ANGIO-PRESS DVT Compression Device meet the requirements of its pre-defined acceptance criteria and intended uses.

5.9 Clinical Testing

No clinical test data was used to support the decision of safety and effectiveness.

5.10 Substantial Equivalence Determination

The ANGIO-PRESS DVT Compression Device is substantially equivalent in intended use, design, technology/principles of operation, materials and performance to the cleared VasoPress DVT Supreme Mini, Pump Model No. VP500DM (K101915). Differences between the devices cited in this section do not raise any new issues of safety or effectiveness.

Item	ANGIO-PRESS DVT Compression Device	VasoPress DVT Supreme Mini, Pump Model No. VP500DM (K101915)
Regulation Number	870.5800	870.5800
Classification	Class II	Class II
Product Code	JOW	JOW
Prescription Use	Yes	Yes
Indications for Use	The Pegasus Medical Supply Inc. ANGIO-PRESS IPCS Deep Vein Thrombosis (DVT) Compression Devices are intended to increase venous blood flow in patients in order to help prevent deep vein thrombosis.	The VasoPress Pump (Model VP500DM) is an external pneumatic compression device for use with VasoPress DVT garments, and is intended to lower the risk of deep vein thrombosis (DVT) in patients who may be at risk.

Model	IPCS	VP500DM
Dimension	12.6” x 4.3” x 7.7”	9.45” x 4.53” x 6.1”
Weight	3.1 kg	2 kg (without Power Cord)
Fuse Rating	1A/250V	1A or T1AH 250V
Pressure Range	Same	40 and 80 mmHg
Input Rating	Same	AC 100-240V, 50/60Hz
Operating Humidity	Same	30 - 75%
Operation Temperature	Same	15°C - 35°C
Applied Part	Same	Garment and Air Hose
Applied Mode of Pressure	Same	Intermittent
Number of Chambers in Garment	Same	No
Inflation time per chamber	Same	12 seconds
Deflation time per chamber	Same	48 seconds
Pressure Range Calf/Thigh	Same	40 mmHg
Pressure Range Foot	Same	80 mmHg
Battery Pack	No	Yes

5.11 Similarity and difference

The difference between the proposed device and the predicate device is the battery pack. For predicate device, VasoPress DVT Supreme Mini, Pump Model No. VP500DM (K101915), the original intention to include battery pack function was to offer user a power solution when device was being used outdoor or during transportation. The system will automatically shift to battery power when the device which has been installed with the battery pack be disconnected from AC power source. Battery pack is an optional feature to VasoPress DVT and AC power source is the main power source.

The main power source of the proposed device, ANGIO-PRESS DVT Compression Device is AC power, same with the predicate device. ANGIO-PRESS DVT Compression Device design does not include battery pack function, so it can't offer an outdoor or transpiration power solution as VasoPress DVT. But ANGIO-PRESS DVT Compression Device can offer the same function as VasoPress DVT which has not been installed with the battery pack. Also, ANGIO-PRESS DVT Compression Device will not change or affect the patient population who is intended to use this device. Therefore, the only difference of the proposed device without the battery pack to the predicate device is that the proposed device is not intended to be used outdoor or on transportation.

The proposed device has tested on safety and performance tests and the results were complied with the test requests. Therefore, the difference of proposed device and predicate device did not raise any problems of safety or effectiveness. The proposed device is substantially equivalent to the predicate device in intended use, design, and performance claims.

5.12 Conclusion

After analyzing bench tests, safety testing data, it can be concluded that ANGIO-PRESS DVT Compression Device is substantially equivalent to the predicate device.